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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,181	09/15/2003	Steven Z. Wu	50623.334	1431
7590 Cameron Kerrigan Squire, Sanders & Dempsey L.L.P. Suite 300 One Maritime Plaza San Francisco, CA 94111-3492			EXAMINER SHEIKH, HUMERA N	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 04/15/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/663,181

Applicant(s)

WU ET AL.

Examiner

Humera N. Sheikh

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25, 27 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 27 and 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION
Status of the Application

Receipt of the Response after Non-Final Office Action, the Amendment and Applicant's Arguments/Remarks, all filed 01/29/08 is acknowledged.

Applicant has overcome the following rejection(s) by virtue of the amendment and/or persuasive remarks: (1) The 35 U.S.C. §102(e) rejection of claims 25-29, 31 and 32 as being anticipated by Golomb *et al.* (U.S. Pat. No. 6,719,998) has been withdrawn.

Claims 25, 27 and 30-33 are pending in this action. Claim 25 has been amended. Claims 1-24 have previously been cancelled. Claims 26, 28 and 29 have been cancelled herein. Claims 25, 27 and 30-33 remain rejected.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 25, 27 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golomb *et al.* (U.S. Pat. No. 6,719,998).

Golomb *et al.* ('998) teach compositions and methods for the treatment of restenosis (see Abstract); (col. 1, lines 7-10); (col. 7, lines 4-14). The method of treatment of restenosis comprises administering an effective amount of active ingredient

Art Unit: 1618

(biphosphonates – (BP) or pyrophosphate), a complex thereof or a pharmaceutically acceptable salt or ester thereof (col. 2, lines 33-67).

The invention provides for the treatment of in-stent restenosis (col. 3, lines 35-50). Golomb *et al.* teach that the active ingredient may be formulated in a manner allowing its incorporation onto the stent, which will yield administration of said active ingredient directly at the site. The active ingredient may be formulated in that manner, for example, by including it within a coating of the stent. Examples of coating are polymer coatings, e.g., made of polyurethane or a gel (col. 3, lines 47-60).

The compositions may be prepared in various forms such as capsules, tablets, aerosols, solutions, suspensions, or as a coating of a medical device such as a stent (col. 3, line 64 – col. 4, line 9).

In a preferred embodiment of the invention, the active ingredient is formulated into a particulate form. This may be achieved by encapsulating or impregnating the active ingredient into particles, e.g., polymeric particles, lipid vesicles or liposomes (col. 4, lines 9-13). Furthermore, such particles may be particles of polymerized active ingredient (col. 4, lines 13-23).

At column 5, lines 55-58, it is taught that pyrophosphate is preferably formulated and administered in a liposome or a polymeric particle preparation.

The composition of the invention may comprise active ingredient either in their free acid form, complexed with metal cations or may be in the form of salts or esters or they may be polymerized to yield polymers of up to 40 monomers. The salts or polymers may be in a micronized particulate form having a diameter within the range of about 0.01-10 μm (col. 5, line 58 – col. 6, line 4).

Art Unit: 1618

Golomb *et al.* teach that the active ingredient may be encapsulated or embedded in inert polymeric particles such as, for example, any of the microcapsules, nanocapsules, nanoparticles, nanospheres, microspheres, microparticles, etc. known in the art. The release of the active ingredient from such particles may be a controlled release, which can result in prolonged and enhanced effect and uptake of the active ingredient (col. 6, lines 18-24).

Pharmaceutical carriers or diluents are disclosed at col. 6, lines 25-37). The composition used for injection may be selected from emulsions, solutions, suspensions, colloidal solutions containing suitable additives, etc. (col. 6, lines 38-40).

The compositions may be administered by any route, which effectively transports the active compound to the appropriate or desirable site of action. Modes of administration include intravenous, intra-arterial and intramuscularly. Local administration can be carried out by means of a suitable oozing/sweating balloon known in the art (col. 6, lines 41-50).

The compositions may be administered by perivascular delivery by coating of the delivery system on a balloon or stent (col. 6, lines 51-62).

The instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Golomb *et al.*

* * * * *

Response to Arguments

Applicant's arguments filed 01/29/08 have been fully considered and were found to be partially persuasive.

▪ **Rejection under 35 U.S.C. §102(e) over Golomb *et al.* (U.S. Pat. No. 6,719,998):**

Applicant argued, “Nowhere does Golomb disclose, either expressly or inherently, a coating material that includes a polymeric material dissolved in a solvent nor does Golomb disclose applying a fluid form of the coating material to a medical device and solidifying the coating material by allowing the solvent to evaporate.”

Applicant’s arguments have been fully considered and were found persuasive by virtue of the amendment to the claims. Accordingly, the §102(e) rejection over Golomb *et al.* (‘998) has been withdrawn.

▪ **Rejection under 35 U.S.C. §103(a) over Golomb *et al.* (U.S. Pat. No. 6,719,998):**

Applicant argued, “There is no mention of a polymeric material dissolved in a solvent as part of a coating material in addition to polymer particles. The Examiner has provided no rationale for modifying the teachings of Golomb so that it teaches the claim limitations. The present invention requires both therapeutic substance-containing polymer particles and a polymeric material dissolved in a solvent to be present in the coating material that is applied to the medical device.”

Applicant’s arguments have been fully considered but were not rendered persuasive. The argument that the prior art teaches a two-polymeric system versus the prior art which teaches a single polymeric material on the device was not persuasive since Golomb explicitly teaches essentially a similar method as is instantly claimed for

Art Unit: 1618

providing a coating onto a medical device, *i.e.*, a stent, whereby the coating has polymeric particles contained therein. Applicant argues that 'Golomb does not teach the use of an additional polymeric material'. While this may be the case, Applicants have not sufficiently demonstrated as to how the use of the additional polymeric material would provide for any unexpected or superior results over the method of coating disclosed by the prior art reference, particularly since the art vividly teaches that their particles are comprised of polymerized active ingredient. See for instance, col. 4, lines 13-23. Applicant's arguments that the present invention is a 2-polymer delivery system, 'one encased in the other' was further not persuasive. The claims have been given their broadest reasonable interpretation. The claims do not require encasement or encapsulation of the polymeric components. The claim merely requires inclusion of a polymer material. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the art is clearly directed to the treatment of restenosis and thus is concerned with addressing the same problems and objectives as claimed by Applicant.

Applicant argued, "Nowhere does Golomb disclose that the polymeric particles can be made by a water-in-oil emulsion method as presently claimed."

This was not found persuasive. Golomb teaches that where a liquid carrier is used, the preparation may be in the form of a syrup, emulsion, liposomes, etc. (col. 6, lines 29-37).

Applicant argued regarding claim 31, which claims a hydrogel consistency. This argument was not deemed persuasive since Golomb recognizes and teaches that their

Art Unit: 1618

polymeric coatings can be made of gel, for example, and thus would also exhibit a hydrogel consistency. See col. 3, lines 59-60.

With regards to the particular active agent, i.e., the radioactive isotope of instant claim 33, the art teaches therapeutically effective agents, utilized in the treatment of restenosis. No patentable distinction is seen in the use of one particular active agent over another, especially since the art is also targeted at methods for improving conditions of restenosis.

For the reasons advanced above, Applicant's arguments were not deemed persuasive. The §103(a) rejection has been maintained.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

hns

April 14, 2008

